PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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WRITTEN OPINION
(PCT Rule 66)

Date of mailing *(day/month/year)*	10.11.2003
Applicant's or agent's file reference: VIB-034-PCT	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP03/01229	07.02.2003	08.02.2002

International Patent Classification (IPC) or both national classification and IPC
C07K16/28, A61K39/395

Applicant
VLAAMS INTERUNIVERSITAIR INSTITUUT VOOR ... et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 08.06.2004

Name and mailing address of the international preliminary examining authority:

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I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*

Description, Pages

1-23 as originally filed

Claims, Numbers

1-3 as originally filed

Sequence listing part of the description, pages:

1-9, as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☒ contained in the international application in written form.
   ☒ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this opinion.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-3 (N, IS, IA)

   because:

   ☒ the said international application, or the said claims Nos. 3 (IA) relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 3 (N, IS,IA) are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☒ the claims, or said claims Nos. 1-2 (N, IS, IA) are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims
Inventive step (IS)	Claims
Industrial applicability (IA)	Claims

2. Citations and explanations

   see separate sheet

Item III

III.1 With respect to claims 1 and 2

Claims 1 and 2 do not meet the requirements of Article 5 and 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, namely the inhibition of the expression and/or activity of prominin-1, which merely amounts to a statement of the underlying problem. Moreover, said claims are not supported by the description as required by Article 6 PCT, as their scope is broader than justified by the description.

Due to the severe objections concerning clarity, support and disclosure by the description an examination of said claims in their present form is not possible (see also III.2-III.5).

III.2 With respect to claim 1

The term "molecule" is defined by the result to be achieved. No information about the chemical nature of said molecule is given. Therefore, said claim is not supported by the description, as its scope is broader than justified by the description. Furthermore, claim 1 does not meet the requirements of Article 5 PCT in that the application as filed neither disclose a method to measure the activity of prominin-1 nor the activity itself. Moreover, the activity of prominin-1 does not appear to be known at all.

III.3 With respect to claim 2

a. The term " a small molecule" used in claim 2 is vague and unclear and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claim unclear (Article 6 PCT).

b. The terms "an antibody", "an RNA aptamer", "a peptide", "a ribozyme", "anti-sense nucleic acids" and "siRNA" are not supported by the description. No single example of said molecules showing the alleged technical feature, i.e. inhibition of the expression or activity of prominin 1, is given. Therefore, claim 2 does not meet the requirements of Article 5 and 6 PCT.

III.4 With respect to claim 3

Claim 3 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(i) PCT).

Moreover, during the regional phase, present claim 3 could be in conflict with Article 53(a) EPC, since present claim 3 encompasses testing the "molecules" in humans.

III.5 With respect to claim 3

The subject-matter of claim 3 does not meet the requirements of Article 6 PCT in that step 3 of the method, which is defined as a method to identify molecules that bind to prominin-1, is not related to identifying a molecule binding to prominin-1. Furthermore, the nucleic acid molecules identified do not bind the prominin-1 molecule, rather they code for proteins, which bind to prominin-1. Therefore, claim 3 is not clear.

Concluding remarks

1. The new claims to be filed should take account of all of the above comments.

2. The amendments should be filed by way of replacement pages. If handwritten amendments are submitted, they should be clearly legible.

3. In the reply, the parts of the application as originally filed which form a basis for the amendments should be indicated (cf. Article 34(2)(b) PCT, last sentence).